Application for

United States Letters Patent

of

Fysh DADD

and

Claudiu TREABA

for

ELECTRODE ARRAY WITH BENDABLE TIP

ELECTRODE ARRAY WITH BENDABLE TIP

CROSS-REFERENCE TO RELATED APPLICATIONS

[01] This application makes reference to and claims priority from the following co-pending Australian Provisional Specification: Australian Provisional Application No. 2003901868, entitled "Electrode Array with Bendable Tip" filed April 17, 2003. The entire disclosure and contents of the above applications are hereby incorporated by reference.

BACKGROUND

Field of the Invention

[02] The present invention relates to electrode arrays for use with prostheses, such as hearing prostheses in which an electrode array is implanted in a cochlea of a recipient.

Related Art

[03] Electrode array devices, such as cochlear implant electrode array devices, generally consist of a plurality of electrode elements which are adapted to apply electrical stimulation to surrounding tissue to stimulate the surrounding nerves. In cochlear implant applications, the electrode array device is implanted within the cochlea of a recipient and applies stimulation to the auditory nerves via a series of electrode elements, in accordance with a set stimulation pattern, controlled by an implanted stimulator unit.

[04] The implanted stimulator unit typically applies the stimulation in a manner which is representative of a detected acoustic signal, such that the stimulation pattern applied by the electrode array device stimulates the auditory nerves and elicits a sensation that closely resembles the natural sensation of the detected acoustic signal.

[05] In this regard, it is important that when implanting electrode arrays in sensitive regions of the body, such as the cochlea, that the electrode array be designed in such a manner as to be flexible enough to reduce damage to the sensitive structures of the surrounding tissue, and yet be rigid enough to ensure that the general shape and form of the electrode array is maintained during the insertion procedure such that the electrode array can perform as intended.

[06] In electrode arrays of the type used for implantation in the cochlea, it has been found that the tip of the array plays an important role during the insertion procedure. In this regard, there have been attempts to design the tip of the electrode array in a manner that reduces the possibility of the tip of the electrode array from puncturing or abrading the sensitive tissues of the cochlea and causing damage to the nerve structures which the implant is attempting to stimulate.

[07] One such early attempt is described in Australian Patent No. 582264 to Clark et al. This patent discloses the provision of tip or distal end of the electrode array being provided with at least one discontinuity that increases the flexibility of the tip. The tip is generally an extension of the existing electrode array and is made from the same material, but is extending beyond the most distal electrode element.

[08] One problem with such a design is that the tips were typically relatively too flexible such that during the insertion process the tip would catch on the wall of the cochlea and cause the array to bend back on itself, thereby potentially causing more damage to the cochlea than would ordinarily be the case should the flexible tip not be provided. Such a situation can also result in an implant being incorrectly positioned from the auditory nerve potentially reducing the effectiveness of the array in capturing and stimulating the appropriate nerves. Further, such a situation where the array folds upon itself can cause unwanted interaction or shorting between electrode elements that may be touching, thereby reducing the number of electrodes that may be operational for stimulation.

[09] Other designs have also considered providing an extended flexible tip of a lead or electrode array to aid in insertion, such as that described in EP 0 919 254 to Bakels et al. However, as mentioned above, such tips have all been designed with flexibility in mind rather than stability of the tip, hence all suffer from similar problems as identified above.

SUMMARY

[10] It is therefore an object of the present invention to provide a tip member for an electrode array that is designed to provide stability and flexibility to the electrode array and to assist in guiding the electrode array during insertion thereof.

[11] According to a first broad aspect of the present invention, there is provided a device comprising: an elongate member including at least one electrode mounted thereon; and a tip member extending distally from a distal end of the elongate member, the tip member comprising a tapered portion tapering distally and a blunt end portion at a distal end of the tapered portion, wherein the tip member is resiliently flexible.

[12] According to a second broad aspect of the present invention, there is provided a tip member comprising: a barrel portion; a tapered portion at a distal end of the barrel portion, the tapered portion tapering distally; and a blunt end portion at a distal end of the tapered portion, wherein the tip member has a substantially uniform bending stress distribution in an axial direction and wherein the tip member has a shape and size that allows the tip member to be in inserted in a human cochlea.

[13] According to a third broad aspect of the present invention, there is provided a method for making a device comprising the steps of: (a) providing an elongate member; and (b) mounting a tip member on the elongate member, wherein the tip member comprises a barrel portion, a tapered portion tapering distally from at distal end of the barrel portion and a blunt end portion at a distal end of the tapered portion, wherein the tip member has a substantially uniform bending stress distribution in an axial direction and wherein the tip member has a shape and size that allows the tip member to be in inserted in a human cochlea.

BRIEF DESCRIPTION OF THE DRAWINGS

[14] The invention will be described in conjunction with the accompanying drawings, in which:

[15] FIG. 1 is a force diagram of a prior art tip member used in electrode arrays;

[16] FIG. 2 is a force diagram of another prior art tip member used in electrode arrays;

[17] FIG. 3A is a side view of a tip member in accordance with an embodiment of the present invention;

[18] FIG. 3B is cross-sectional view of the tip member of FIG. 3A, taken along line B—B.

[19] FIG. 4A is a cross-sectional view of an electrode array device in accordance with one embodiment of the present invention in which tip member of FIGS. 3A and 3B are mounted

on an elongate member with only a portion of the elongate member being shown for simplicity;

[20] FIG. 4B is an end-on view of the electrode array device of FIG. 4A;

[21] FIG. 5 is a simplified side elevational view of the electrode array device of FIGS. 4A and 4B of the present invention depicted in an intermediate orientation;

[22] FIG. 6 is a simplified part sectional, part side elevational view of the electrode array device of FIGS. 4A and 4B depicted in its pre-formed orientation following insertion in the cochlea;

[23] FIG. 7 is a simplified side elevation view of an electrode array device in accordance with another embodiment of the present invention depicted in an intermediate orientation; and

[24] FIG. 8 is a cross-sectional view of an electrode array device in accordance with one embodiment of the present invention in which tip member of FIGS. 3A and 3B are mounted on an elongate member with only a portion of the elongate member being shown for simplicity.

DETAILED DESCRIPTION

[25] It is advantageous to define several terms before describing the invention. It should be appreciated that the following definitions are used throughout this application.

Definitions

[26] Where the definition of terms departs from the commonly used meaning of the term, applicant intends to utilize the definitions provided below, unless specifically indicated.

[27] For the purposes of the present invention the term "uniform bending stress distribution" refers to the conventional meaning of the term uniform bending stress distribution. For example, a tip member that has uniform bending stress distribution may be envisioned as a constant-strength cantilever beam where bending stresses throughout the beam are equal to those at the fixed end, that is, the junction of the tip member with the elongate member on which the tip member is mounted.

[28] For the purposes of the present invention, the term "distal" refers to the end of a device or the end of a part of a device that is to be inserted into a cochlea.

[29] For the purposes of the present invention, the term "tapering distally" refers to a device or part that is tapered and in which the diameter of the device or part is smaller at the distal end of the device or part than at the proximal end of the device or part.

[30] For the purposes of the present invention, the term "proximal" refers to the end of a device or the end of a part of a device that is at the opposite end of the device or the part of device from the distal end.

[31] For the purposes of the present invention, the term "axial direction" refers to a line extending through a device between the distal end of the device to the proximal end of the device in either direction.

[32] For the purposes of the present invention, the term "axis" refers to the conventional meaning of the term "axis", *i.e.* a line through the middle of a device or part of a device. The "long axis" of a device or part of a device is the longest axis that may be drawn through a device or part of device. In the devices of the present invention, the long axis usually extends between the proximal end and the distal end.

[33] For the purposes of the present invention, the term "cylindrical" refers to the general meaning of the term "cylindrical". The term "substantially cylindrical" refers to any part of a device having a generally cylindrical shape. For example, a part of a device may be substantially cylindrical and still include various raised or etched surface patterns and/or textures and may vary in width throughout the length of the part as long as the object has roughly the same diameter at the proximal and distal ends of the part.

[34] For the purposes of the present invention, the term "frusto-conical" refers to the general meaning of the term "frusto-conical". The term "substantially frusto-conical" refers to any part of a device having a generally frusto-conical shape. A part of a device may be substantially frusto-conical and still include various raised or etched surface patterns and/or textures and may taper non-continuously as the object has a proximal or distal end that is narrower than the opposite end of the part.

[35] For the purpose of the present invention, the term "continuous taper" refers to a part that tapers at a set rate throughout the length of the part. For example, a tapered portion of a tip member that is frusto-conical has a continuous taper in which the diameter of the tapered portion decreases at a fixed rate from the proximal end of the tapered portion to the distal end of the tapered portion. An example of a tapered portion of a tip member of the present invention having a continuous taper is illustrated in FIG. 5.

[36] For the purposes of the present invention, the term "non-continuous taper" refers to a part that does not taper at a set rate throughout the length of the part. For example, a part that is substantially frusto-conical may have regions where the width of the part remains constant without tapering, but which, viewed as a whole, tapers from one end to the other end of the part in an axial direction.

[37] For the purposes of the present invention, the term "notional diametrically opposed sides" refers to the two opposing angled edges formed by cutting a tapered portion of a tip member of the present invention in half along the tapered portion's axis. The angle between two notional diametrically opposed sides is the angle formed by extending two lines from the opposed sides, one line from each side, in a distal direction until the lines meet.

[38] For the purposes of the present invention, the term "blunt" refers to the usually meaning of the term blunt, *i.e.* not sharp. The blunt end of a tip member of the present invention may be convex or concave. The blunt end may be rounded, such as part-spherical, part-ellipsoidal, part-paraboloidal, *etc.*

[39] For the purposes of the present invention, the term "part-spherical" refers to a shape formed by cutting through a sphere to form two parts. For example, a hemisphere would be a part-spherical shape formed by cutting a sphere in half to form two parts.

[40] For the purposes of the present invention, the term "part-ellipsoidal" refers to a shape formed by cutting through an ellipsoid. A part-ellipsoidal shape may be formed by cutting an ellipsoid in half or by cutting an ellipsoid in two form two unequally sized parts.

[41] For the purposes of the present invention, the term "part-paraboloidal" refers to a shape formed by cutting through a paraboloid.

[42] For the purposes of the present invention, the term "resiliently flexible" refers to a flexible tip member than will not undergo fold-over or bend backwards during insertion into a cochlea when exposed to usual insertion forces necessary to insert a tip member of an electrode array into a cochlea.

Description

[43] In one embodiment, the present invention provides an implantable tissue stimulating device, such as a electrode array device, comprising: an elongate electrode carrier member (elongate member) having a body having a first end, and a resiliently flexible tip member extending distally from a distal end of the body. The elongate member has at least one electrode mounted thereon to apply a preselected tissue stimulation, such stimulation of a nerve in a cochlea. The tip member includes a tapered portion tapering distally and a blunt end at a distal end of the tapered portion. In one embodiment of the present invention, the tip member includes a barrel portion at a proximal end of the tip member and the tapered portion extends distally from a distal end of the barrel portion. In a preferred embodiment, the tip member has a length of about 1.2 mm.

[44] In one embodiment of the present invention, the tip member may be formed of the same material as the body of the elongate member. In another embodiment, the tip member may be formed of a different material to that of the body of the elongate member.

[45] The tip member may be formed separately to the body of the elongate member and mounted thereto. For example, the tip member may be adhered using an adhesive to the first end of the body of the elongate member. Alternatively, the tip member may be mounted on the tip member by other means such as by snapping the tip member over a mating distal end portion of the elongate member, screwing the tip member onto the end a threaded distal end of the elongate member, hot welding together the tip member and the elongate member, *etc.* In another embodiment, the tip member may be integrally formed with the body of the elongate member. The tip member may be formed from a silicone material. In another embodiment, the tip member may be formed of an elastomeric material, such as polyurethane. In general, the tip member is made of any material that allows the tip member to be resiliently flexible.

[46] In some embodiments the barrel portion of the tip member may be part of a separate tip member that is joined to an elongate member, such as the embodiment of the present invention illustrated in FIGS. 5. In other embodiments, the tip member may be formed as part of an elongate member, such as the embodiment illustrated in FIG. 7. The elongate member may also have a taper, but the tapered portion of the tip member will taper at a faster rate than the overall taper of the elongate member. Examples of tapered elongate members are illustrated in FIGS. 5 and 7.

[47] In one embodiment of the present invention, the barrel portion of a tip member may be substantially cylindrical in form for a portion of its length. In another embodiment, the barrel portion may be substantially cylindrical in form. In other embodiments the barrel portion may be various shapes and include various types of contouring. The barrel portion also may have various types of cross-section besides the circular cross-section of a cylindrical barrel. For example, the barrel portion may be elliptical in cross-section, rectangular with rounded corners in cross-section, triangular with rounded corners in cross-section, *etc.*

[48] The barrel portion in some embodiments may be slightly tapered, but in such embodiments the tapered portion tapers at a faster rate than the barrel portion.

[49] In one embodiment of the present invention, the barrel portion is about or exactly 0.4mm in length from the proximal end of the barrel portion to the distal end of the barrel portion where the tapered portion begins. In one preferred embodiment where the barrel portion is cylindrical, the diameter of the barrel portion may be exactly or about 0.45mm.

[50] In one embodiment for use with a tip member having a barrel portion with a 0.45 mm diameter the elongate member on which the tip member is mounted is slightly tapered and has a maximum diameter at its proximal end of about 0.80 mm and a minimum width or diameter at its distal end of about 0.5 mm. When the diameter of the distal end of the elongate member is larger diameter of the barrel portion or a different cross-sectional shape, such as illustrated in the embodiment of FIGS. 4A and 4B, various means may be used to ensure a smooth transition between the distal end of the elongate member and the barrel portion. For example, when a silicone adhesive is used to adhere the tip member to the elongate member, some of the silicone adhesive may be used on the surface of the barrel portion to taper to form tapered region filling the gap between the edges of the elongate member and the edges of the barrel portion as shown in FIG. 4A.

[51] The barrel portion preferably includes a lumen therein that extends for some or all of its length of the barrel portion. An example of such lumen is shown in the embodiment of the present invention illustrated in FIG. 3B. In one preferred embodiment, the lumen may be about 0.3mm and have a diameter of about 0.125mm. The lumen may be adapted to receive the distal end of a stiffening element, such as a stylet of the type typically used with cochlear implants. An example of a distal end of a stiffening element being received by a lumen is shown in the embodiment of the invention illustrated in FIG. 4A. The barrel portion preferably has a lumen therein that extends for some or all of its length. In one embodiment of the present invention, the lumen may be about 0.3 mm.

[52] In one embodiment of the present invention, the tapered portion may be substantially frusto-conical in shape. In another embodiment, the tapered portion is frusto-conical in shape. In other embodiments, the tapered portion may be various tapered shapes that are continuously tapered or non-continuously tapered.

[53] In one preferred embodiment, the tapered portion of the tip member may be frusto-conical and has a length of about 0.76mm and the diameter of tapered portion decreases from about 0.45mm to exactly or about 0.2mm. In one embodiment, the angle between notional diametrically opposed sides of a tapered portion that is frusto-conical is about or exactly about 18.9°. In another embodiment the frusto-conical tapered portion may have a length of about 0.76 mm. Over this length, the diameter of the frusto-conical portion decreases from 0.45 mm to 0.2 mm.

[54] Although one type of tapered portion of the present invention is described above, the tapered portion of the present invention may have a shape other than frusto-conical and taper portions that are frusto-conical or substantially frusto-conical may have an angle between notional diametrically opposed sides that is greater or less than 18.9°.

[55] In one embodiment of the present invention, the blunt end of the tip member is round in shape. In another embodiment, the blunt end of the tip member is part-spherical for a portion of its length. In other embodiments the blunt end may have various blunt shapes, both convex and concave, such as part-ellipsoidal, part-paraboloidal, *etc.*

[56] In one preferred embodiment, the blunt end is part-spherical in shape and has length of about 0.04mm and a maximum diameter of about 0.2 mm where the blunt end meets the distal end of the tapered portion.

[57] In one embodiment the tip member of is designed so that when the tip member is subject to a bending force, the moment of that force may be evenly distributed along the tip member and the bending stresses on the tip member are constant throughout its length. This even distribution provides a tip member that is resiliently flexible, *i.e.* that is not subject to foldover when the tip member is subject to a bending force, such as may occur during insertion of the tip member into a recipient of the device.

[58] In one embodiment the tissue-stimulating device may be a prosthetic hearing implant, such as a Cochlear™ implant made by Cochlear Limited, with the elongate member comprising a carrier member for a plurality of electrodes. The tip member in this embodiment may be constructed to assist in the guiding of the elongate member into the cochlea, particularly into the scala tympani of the cochlea.

[59] In another embodiment the elongate member may have a first configuration selected to allow the elongate member to be inserted into a recipient's body and at least a second configuration wherein the elongate member is adapted to apply the preselected tissue stimulation. In one embodiment of the present invention, the elongated member in the first configuration is straight or substantially straight. However, in other embodiments, the elongated member in the first configuration may be curved.

[60] In one embodiment of the present invention, the second configuration of the elongate member is curved. In another embodiment, the elongate member adopts a spiral configuration when in the second configuration. The body of the elongate member may be preformed from a plastic or rubber material with memory that is preformed to the second configuration.

[61] The elongate member may be formed from a resiliently flexible material. In a further embodiment, the tip member is resiliently flexible. In one embodiment of the present invention, the tip member may be formed of a material having substantially the same or the same flexibility as the material used to form the body of the elongate member that encapsulates the electrode element(s) and wires.

[62] In one embodiment of the present invention, the tip member may be formed of the same material as the body of the elongate member. In another embodiment, the tip member may be formed of a different material to that of the body of the elongate member. For example, the tip member may be formed of a material having a relatively lesser stiffness than a portion of the body of the elongate member. In another embodiment, the tip member may

be formed of a material that undergoes a change in stiffness, preferably a decrease in stiffness, on insertion into the body, such as the cochlea.

[63] The tip member may be made as a separate unit and then mounted on to a distal end of the elongate member. For example, the tip member may be adhered to the distal end of the body of the elongate member or be molded thereto in a secondary molding step. In one embodiment of the present invention, the tip member may be formed of an elastomeric material, such as polyurethane. The tip member may also be formed from a silicone material. In general the tip member may be made from any material such as plastic or rubber that allows the tip member to be resiliently flexible.

[64] In one embodiment of the present invention, the body of the elongate member may be formed from a suitable biocompatible material. In one embodiment of the present invention, the material may be a silicone. In another embodiment, the body may be formed from a suitable elastomeric material, such as a polyurethane or other biocompatible rubbers or plastics.

[65] In another embodiment, the elongate member may have a receiving portion into which a stiffening element may be inserted. The device may also further include a removable stiffening element positionable within the receiving portion of the elongate member and having a configuration selected for biasing the elongate member into the first configuration, described above. The stiffening element is preferably relatively stiffer than the elongate member.

[66] In one embodiment of both aspects, the receiving portion may comprise a lumen extending at least into, and more preferably through, the body of the elongate member. The lumen for the stylet may be cylindrical and also may have an opening formed therein proximal to the tip member. In the case of a metal stylet, the stylet may extend out of the opening allowing the stylet to be manipulated and removed from the lumen during or following insertion of the device.

[67] In one embodiment the stiffening element is formed of a bioresorbable material which dissolves on exposure to a fluid. The stiffening element may dissolve on exposure to a saline solution or a body fluid of the implantee, such as cochlear fluid. In another embodiment, the bioresorbable material of the stiffening element is selected from the group consisting of

polyacrylic acid (PAA), polyvinyl alcohol (PVA), polylactic acid (PLA) and polyglycolic acid (PGA).

[68] In one embodiment of the present invention, the stiffening element may comprise a stiffening element formed from a non-bioresorbable material. In this embodiment, the stiffening element may comprise a metallic stylet extending through the receiving portion of the body of the elongate member. In one embodiment of the present invention, the wire may be formed from a biocompatible metal or metallic alloy. In one embodiment of the present invention, the stylet may be formed from platinum. Other suitable stiffening elements and stylets for use in the present invention are also described in U.S. Patent No. 6,421,569, U.S. Patent Application No. 10/070,102 filed July 8, 2002, and U.S. Patent Application No. 10/203,279 filed October 17, 2001, the entire disclosures and contents of which are hereby incorporated by reference.

[69] In one embodiment of the present invention, the stiffening element may be formed from a shape memory or heat sensitive material. For example, the stiffening element may be formed from a bimetallic element (such as nickel/titanium) and shaped to take a straight or substantially straight configuration at room temperature but bends into another shape once it is exposed to body temperature.

[70] The construction of the electrode array device of the present invention may be adapted to minimize the likelihood of trauma to the cochlea caused by insertion of the electrode array device. The construction of the tip member is envisaged by the present inventors to assist in guiding the electrode down the lumen of the scala tympani of the cochlea. It is also envisaged that the construction of the tip member will minimize the potential for the tip member of the electrode to perforate the basilar membrane of the cochlea or damage other sensitive structures in the cochlea.

[71] The tip member of the present invention is useful for those elongate members inserted in the cochlea using an Advance Off-Stylet™ (AOS™) mode of implantation. In this mode, the elongate member while mounted on a stylet is inserted through a cochleostomy until the tip member is positioned just short of the basal turn of the cochlea. Once the tip member has reached this position, the elongate member may be advanced or moved off the stylet and further into the scala tympani. As the elongate member is advanced off the stylet, the elongate member is also free to begin to adopt its preferential spiral curvature. The

construction of the tip member of the present invention prevents foldover of the tip member as the tip member is moved off the stylet. The length of the tip member, however, is also sufficiently short to ensure that the tip member does not damage the walls of the scala tympani once the elongate member has reached its desired final insertion position in the cochlea.

[72] FIGS. 1 and 2 represent force diagrams of typical tip members of known prior art electrode array carriers. It is possible from a review of these two diagrams to identify the problems with such prior art tip members.

[73] FIG. 1 illustrates a prosthetic hearing implant device 100 including a tip member 102 is essentially an extension of an electrode array carrier member 104. For simplicity, only a portion of electrode array carrier member 104 is illustrated in FIG. 1. Electrode 106 is the most distal electrode of electrode array carrier member 104. Tip member 102 has a bulbous distal end 108 a relatively narrow diameter neck section 112 which is designed to provide increased flexibility to tip member 102. As is shown, during insertion a force, (represented by arrow 122) is applied to tip member 102 when electrode array carrier member 100 comes into contact with the wall of the cochlea (not shown) during insertion. Due to the force represented by arrow 122, tip member 102 will flex about neck section 112 causing distal end 108 to undergo excessive deflection, indicated by ghost lines 124, greatly increasing the possibility of tip member 102 folding over upon itself during insertion.

[74] FIG. 2 illustrates a prosthetic hearing implant device 200 including a tip member 202 having a constant cross-sectional diameter d2 along the length of tip member 202. Similarly tip member 102 shown in FIG. 1, tip member 202 is essentially an extension a carrier member 204 for the electrode array (not shown) beyond the position of the most distal electrode (not shown). As is shown, when a force represented by arrow 222 is applied to a distal end 228 of tip member 202, tip member 202 will flex about a location 230 where tip member 202 joins carrier member 204.

[75] The design of the implant device illustrated in FIG. 2 increases flexibility due to the long arm of the impact force and as such there is an increased risk of such a tip member design causing array foldover and potential damage to the sensitive structures of the cochlea.

[76] FIGS. 3A and 3B represents one embodiment of a tip member 302 of the present invention. Tip member 302 includes a cylindrical barrel portion 304, a frusto-conical tapered

portion 306 at a distal end 308 of barrel portion 304 and a part-spherical blunt end 310 at distal end 312 of tapered portion 306. Blunt end 310 terminates at tip member distal end 314. Within cylindrical barrel portion 304 is a lumen 314 for receiving a stiffening element (not shown). Cylindrical barrel portion 304 has diameter 318 that is constant. In contrast, tapered portion 306 has a diameter that continuously decreases along the length of tapered portion 306, as illustrated by exemplary diameters 320 and 322. Tip member 302 is attached to a carrier member (not shown in FIG. 3) at a proximal end 330 of tip member 302. An angle 332 between notional diametrically opposed sides 334 and 336 of tapered portion 306 is 18.9°. Lumen 314 has a constant diameter 342.

[77] In the embodiment depicted in FIGS. 3A and 3B, the tip member is constructed separately from the carrier member carrying the electrode array. This allows the tip member to more easily be constructed in a manner that ensures the parameters of the tip member are appropriately controlled to ensure that the tip member fulfils its designed purpose.

[78] The tip member depicted in FIGS. 3A and 3B, may be constructed of any material that allows the tip member to be resiliently flexible.

[79] The dimensions and shape of tip member shown in FIGS. 3A and 3B allows for smooth insertion of an electrode array to which the tip member is attached while preventing tip member foldover.

[80] In one embodiment of the present invention, the barrel portion of the tip member shown in FIGS. 3A and 3B may be exactly or about 0.4 mm in length and the diameter of the barrel portion may be exactly or about 0.45 mm for all or at least some of its length.

[81] In one embodiment, the lumen in the tip member of FIGS. 3A and 3B has a diameter of about 0.125 mm and a length of about 0.3 mm.

[82] In one embodiment of the present invention, the tapered portion of the tip member of FIGS. 3A and 3B has a length of about 0.76 mm and over this length the diameter of the tapered portion decreases from about 0.45 mm to 0.2 mm.

[83] In one embodiment of the present invention, the length of the part-spherical blunt end has a length of about 0.04 mm and over this length blunt end decreases from about 0.2mm to 0.0 mm at the very distal end of the blunt end.

[84] FIGS. 4A and 4B illustrates a electrode array device 400 in accordance with one embodiment of the present invention. Electrode array device 400 includes tip member 302 mounted on an elongate member 402, only a portion of which is shown in FIG. 4A. Elongate member 402 includes a lumen 404 extending therethrough. Tip member 302 is held on elongate member 402 by means of a liquid silicone rubber adhesive 406. Filler portions 408 of adhesive 406 smooth the transition from elongate member 402 to tip member 302, because in this embodiment a distal end 410 of elongate member 402 has a larger diameter than tip member proximal end 330. For illustration purposes, the amount of adhesive 406 between elongate member distal end 410 and tip member proximal end 330 is exaggerated in the depiction in FIG. 4A. A stylet 422 inserted into elongate member extends through lumen 404 and into lumen 314 of tip member 302. Elongate member 402 is slightly tapered, but the taper is of elongate member 402 is not as great as the taper of tapered portion 306 of tip member 302. Elongate member 402 includes electrodes 432 on one side of elongate member 402. During insertion into a cochlea (not shown), tip member 302 may be subject to a impact/deflection force represented by arrow 442. As illustrated in FIG. 4B, elongate member 402 has a rounded corner square shaped cross-section having a minimum width 452.

[85] As illustrated in FIG. 4A, the tip member provides a smooth transition of flexibility from the relatively stiff portion of the carrier member containing the electrode elements and wires (not shown) to the more flexible blunt end of the tip member.

[86] Although the elongate member shown in FIG. 4B has a rounded corner square shaped cross-section, the elongate member of the present invention may have various cross-sectional shapes such as circular, elliptical, rectangular, *etc.* and the cross-sectional shape of the elongate member may vary over the length of the elongate member.

[87] FIG. 5 illustrates electrode array device 400 in a curved orientation. Upon insertion of electrode array device 400 into the scala tympani of the cochlea (not shown), the exposure of electrode array device 400 to body temperature (about 37°C.) results in stylet 422 adopting a curved orientation. As stylet 422 adopts a curved orientation, elongate member 402 is free to also adopt the curved orientation as is depicted in FIG. 5.

[88] As the elongate member 402 curls, the surgeon may continue to further insert electrode array device 400 into scala tympani 622 of a cochlea 624 as illustrated in FIG. 6. During the further insertion process, the surgeon may commence withdrawal of stylet 422

from lumen 404 of elongate member 402. Alternatively, the surgeon may withdraw stylet 422 following complete insertion of electrode array device 400 into its final position, this decision being dependent of the surgeon's preferences. Upon withdrawal of stylet 422, elongate member 402 is free to adopt its pre-formed spiral orientation, as depicted in FIG. 6, with electrodes 432 (not visible in FIG. 6) facing the modiola (not visible in FIG. 6) within cochlea 624 so that electrodes 432 are positioned as close as possible to the spiral ganglia thereof.

[89] FIG. 7 illustrates a electrode array device 702 of the present invention including a tip member 704 that is integral with an elongate member 706. A stylet 708 is inserted through a lumen in elongate member 706 and into a lumen in tip member 704. Electrode array device 702 is essentially similar to electrode array device 400 in both structure and function, except that tip member 704 is integral with elongate member 706 whereas in electrode array device 402 tip member 302 is mounted on elongate member 402. As illustrated in FIG. 7, electrode array device 702 is in a curved orientation, similar to the curved orientation of electrode array device 400 in FIG. 5.

[90] While an elongate member of the present invention, such as the elongate members of FIG. 5 and FIG. 7, may be manufactured with a preformed curved orientation, the device is typically delivered to a surgeon with the stylet in place. The stylet, while at room temperature, holds the elongate member in a straight orientation. A useful stylet for the purposes of the present invention may be a Nitinol wire.

[91] FIG. 8 illustrates an electrode array device 800 in accordance with one embodiment of the present invention. Electrode array device 800 includes tip member 302 mounted on an elongate member 802, only a portion of which is shown in FIG. 8. Elongate member 802 includes a lumen 804 extending therethrough. A distal end 810 of elongate member 802 has the same size diameter and is the same shape as tip member proximal end 330, so there is a smooth transition between elongate distal end 810 and tip member proximal end 330. A stylet 822 inserted into elongate member extends through lumen 804 and into lumen 314 of tip member 302. Elongate member 802 is slightly tapered, but the taper is of elongate member 802 is not as great as the taper of tapered portion 306 of tip member 302. Elongate member 802 includes electrodes 832 on one side of elongate member 802. During insertion into a cochlea (not shown), tip member 302 may be subject to an impact/deflection force represented by arrow 842.

[92] In the electrode array device of the present invention, such as the cochlear implant devices illustrated in FIGS. 5, 6 and 7 the stylet may have a preferred direction of curl on exposure to body temperature within the cochlea. In one embodiment, the device may have an indicia means that provides an indication to a user, such as a surgeon, of the preferred direction of curl of the device on implantation. This may be important as the device is preferably oriented in the cochlea such that the direction of curl results in the device being able to be moved into the scala tympani. The indicia means may comprise a loop formed in the wire at or adjacent a distal end thereof. The loop as well as acting as an indicia means may act as a means of engaging with and withdrawing the stylet from the lumens in the elongate member and tip member during or following implantation. In one embodiment, the loop may be in the same plane as the preferred direction of curl of the stylet. The loop may extend away from the preferred direction of curl of the stylet.

[93] In one embodiment of the present invention, it is possible to provide a sheath of bioresorbable and lubricious material, similar to the sheath described and shown in U.S. Patent Application No. 10/203,079, the entire disclosure and contents of which is hereby incorporated by reference. The bioresorbable material of stiffening sheath may be polyacrylic acid (PAA) that is adapted to dissolve on exposure to cochlear fluids. Other suitable bioresorbable materials may be envisaged and such materials need not necessarily dissolve on exposure to fluids. For example, the sheath may be made of a material that softens upon exposure to fluids but does not get absorbed.

[94] As mentioned above, in one embodiment of the present invention, the tip member may be constructed separately from the elongate member of electrode array device. In this regard, the tip member may be constructed out of a similar material to the body of the electrode array carrier such as silicone. To aid in fixing the tip member to the elongate member during production, the tip member lumen may be used to fit over a production stylet positioned within the lumen of the elongate member of the electrode array device during its manufacture. Such a production stylet may be placed in a mold, along with the electrodes, and a suitable quantity of silicone is then poured into the mould around the stylet and electrodes to form the elongate member. In the present embodiment, the distal end of the production stylet would preferably extend a relatively short distance out of the distal end of the molded carrier member and act as a support for the tip member lumen of the tip member when the tip member is subsequently securely mounted on the distal end of the elongate

member. A suitable production stylet and a method of manufacturing the elongate member of the electrode array device of the present invention is described in more detail in U.S. Patent No. 6,421,569, the entire disclosure and contents of which is hereby incorporated by reference.

[95] Suitable elongate members for use with the tip member of the present invention and methods for inserting a device of the present invention into a cochlear are described in U.S. Patent No. 6,421,569, U.S. Patent Application No. 10/070,102 filed July 8, 2002, and U.S. Patent Application No. 10/203,279 filed October 17, 2001, the entire disclosures and contents of which are hereby incorporated by reference.

[96] The present invention provides a specifically designed tip of a electrode array device that is shaped and dimensioned in a manner to optimize the flexibility of the array such that the tip will not undergo fold-over during insertion when exposed to usual insertion forces. This invention is a significant improvement over prior art attempts at providing such a flexible tip as embodiments of the present invention overcome the problem of the tip being too flexible at a critical section and becoming too flexible to enable smooth insertion of the array.

[97] The present invention will now be described by way of example:

Example

[98] In one embodiment of the tip member of the present invention having a shape such as shown in FIGS. 3A and 3B, the design of the tip member may be based upon establishing the dimensions of three main parameters:

Dl is the diameter of the proximal end of the tip member that is connected to the elongate member;

D2 is the diameter of the distal end of the frusto-conical tapered portion; and

L is the length of the tip member.

[99] The diameter D1 of the tip member in this embodiment at its proximal end that is connected to the end of the elongate member is preferably exactly or about 0.45mm. This diameter allows the tip member to be easily fitted onto the end of a conventional electrode

array device, such as the Contour electrode array device manufactured by Cochlear Limited of Lane Cove, New South Wales, Australia.

[100] The diameter D2 of the distal end of the frusto-conical tapered portion of the tip member in this embodiment is preferably exactly or about 0.2 mm. This diameter has been determined based upon studies and experimental measurements of human cochlea and the sizes of the diameter of the outer wall of the cochlea as a dimension most likely to minimize the chance of the tip member penetrating the outer wall.

[101] The length L of the tip member in this embodiment is preferably exactly or about 1.2mm. Again, this dimension has been determined as being suitable for ensuring the tip fits within the appropriate region inside the cochlea for a range of initial electrode array insertion depths. It has been found that such a length of the tip member minimizes the likelihood of, and more preferably avoids, tip foldover for typical forces associated with electrode array insertion.

[102] Having determined the important parameters of the tip of the present invention, namely D1, D2 and L, the shape of the tip in this embodiment provides great flexibility whilst providing smooth mechanical interaction between the tip and the cochlea thereby providing a smooth insertion procedure. The shape of the tip member in this embodiment takes into consideration the mechanical design requirements of the tip member. The shape and dimensions of the tip member of this embodiment is based on the idea of treating the tip member as a cantilever beam and determining the dimensions of a constant-strength cantilever beam where bending stresses throughout the beam are equal to those at the fixed end, that is, the junction of the tip member with the elongate member.

[103] In this regard, the general stress formula for such a cantilever beam (assuming a rectangular cross-section) is:

$$\sigma = 6FL/(bh^2)$$

where σ is the stress;
F is the deflection/impact force; and
L,b,h are the beam length, fixed end width, and height, respectively.

[104] Assuming that the tip member is attached to a substantially tubular elongate member, the preferred cross-section of the tip is circular, so that there is maximum alignment between the elongate member and the tip member when the tip is attached to the elongate member during production. In this regard, for a circular beam the constant stress formula may be written as:

$$\sigma = k(\text{const.}) \times ((F.x)/D^3)$$

where x is arm of force F (see FIG. 4A); and
D is the diameter for the circular beam.

[105] Therefore, for a given impact/deflection force F (constant), in order to achieve uniform strength the following formula may be found:

$$X/D^3 = k' \text{ (const.)}$$

[106] Therefore the formula for D as a function of x is:

$$D = k''(\text{const.}) \times \text{cube root } (x)$$

[107] Given the abovementioned established parameters of the tip, namely D1 D2 and L, the following equations may be determined:

$$0.2 = k''(\text{const}) \times \text{cube root}(x)$$
$$0.45 = k''(\text{const}) \times \text{cuberoot } (x = 1.2)$$

[108] As a result, in order to control the distribution of the force over the length of the tip, the shape of the tip member of this embodiment may be approximated to the partially frusto-conical tapered shape as depicted in FIG. 3A.

[109] All documents, patents, journal articles and other materials cited in the present application are hereby incorporated by reference.

[110] Although the present invention has been fully described in conjunction with several embodiments thereof with reference to the accompanying drawings, it is to be understood that various changes and modifications may be apparent to those skilled in the art. Such changes

and modifications are to be understood as included within the scope of the present invention as defined by the appended claims, unless they depart therefrom.